



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2015-N-1338]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Rectal Control System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the rectal control system into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the rectal control system's classification.

The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on February 12, 2015.

FOR FURTHER INFORMATION CONTACT: Purva Pandya, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G223, Silver Spring, MD, 20993-0002, 240-402-9979, purva.pandya@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification

request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On June 23, 2014, Pelvalon, Inc., submitted a request for classification of the Eclipse System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 12, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5930.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a rectal control system will need to comply with the

special controls named in this final order. The device is assigned the generic name rectal control system, and it is identified as a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an external regulator to control the state of expansion.

FDA has identified the following risks to health associated specifically with this type of device, as well as the measures required to mitigate these risks in table 1.

Table 1.--Rectal Control System Risks and Mitigation Measures

Identified Risk	Mitigation Measures
Vaginal Wall Trauma	Clinical Testing Labeling
Adverse Tissue Reaction	Biocompatibility Testing
Infection	Non-Clinical (Bench) Testing Cleaning and Disinfection Validation Labeling
Device Malfunction	Non-Clinical (Bench) Testing Labeling
Urinary Urgency, Incontinence, or Voiding Problems	Clinical Testing Labeling
Fecal Urgency or Difficulty in Evacuation	Clinical Testing Labeling
Discomfort, Pain	Clinical Testing Labeling
Change in Amount, Color, or Consistency of Vaginal Discharge	Labeling

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

- Clinical testing must document the device acceptance data and the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.
- The elements of the device that contact vaginal tissue must be demonstrated to be biocompatible.

- The cleaning and disinfection instructions for the device must be validated.
- Non-clinical (bench) testing must demonstrate that the device performs as intended under anticipated conditions of use.
- Non-clinical (bench) testing must demonstrate that the device does not:
 - Enhance the growth of Staphylococcus aureus.
 - Increase production of Toxic Shock Syndrome Toxin-1 by S. aureus.
 - Alter the growth of normal vaginal flora.
- Labeling must include:
 - Specific instructions, contraindications, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.
 - The intended patient population and the intended use environment.
 - Information on how the device is to be fitted, how the device operates, and recommendations on device maintenance.
 - A detailed summary of the clinical testing pertinent to the use of the device, including a summary of the device- and procedure-related complications or adverse events related to use of the device, as well as relevant safety and performance information.
- Patient labeling must be provided and must include:
 - Relevant contraindications, warnings, precautions, and adverse events/complications.
 - Information on how the device operates and the recommended device maintenance (i.e., care instructions), including cleaning and disinfection.
 - Information on the patient population for which there was a favorable benefit/risk assessment.
 - The potential risks and benefits associated with the use of the device.

Rectal control system devices are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (Prescription devices).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the rectal control system they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120,

and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910-0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. DEN140020: De Novo Request per 513(f)(2) from Pelvalon, Inc., dated June 23, 2014.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876--GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 876.5930 to subpart F to read as follows:

§ 876.5930 Rectal control system.

(a) Identification. A rectal control system is a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an external regulator to control the state of expansion.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Clinical testing must document the device acceptance data and the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(2) The elements of the device that contact vaginal tissue must be demonstrated to be biocompatible.

(3) The cleaning and disinfection instructions for the device must be validated.

(4) Non-clinical (bench) testing must demonstrate that the device performs as intended under anticipated conditions of use.

(5) Non-clinical (bench) testing must demonstrate that the device does not:

(i) Enhance the growth of Staphylococcus aureus.

(ii) Increase production of Toxic Shock Syndrome Toxin-1 by S. aureus.

(iii) Alter the growth of normal vaginal flora.

(6) Labeling must include:

(i) Specific instructions, contraindications, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.

(ii) The intended patient population and the intended use environment.

(iii) Information on how the device is to be fitted, how the device operates, and recommendations on device maintenance.

(iv) A detailed summary of the clinical testing pertinent to the use of the device, including a summary of the device- and procedure-related complications or adverse events related to use of the device, as well as relevant safety and performance information.

(7) Patient labeling must be provided and must include:

- (i) Relevant contraindications, warnings, precautions, and adverse events/complications.
- (ii) Information on how the device operates and the recommended device maintenance (i.e., care instructions), including cleaning and disinfection.
- (iii) Information on the patient population for which there was a favorable benefit/risk assessment.
- (iv) The potential risks and benefits associated with the use of the device.

Dated: May 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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